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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/876,680	06/07/2001	Wade Blair	3053-4087	8187

7590 01/23/2003

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345 Park Avenue  
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EXAMINER
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HILL, MYRON G

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 01/23/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n N .

09/876,680

Applicant(s)

BLAIR ET AL.

Examiner

Myron G. Hill

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1- 23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1- 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

This action is on claims 1- 23.

#### ***Information Disclosure Statement***

Supplemental IDS mailed 5 March 2002 does not contain a PTO-1449; however, the item is being cited in the office action so a replacement is not required. The first IDS is signed, copied, and returned with this office action.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 10, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Haseltine.

Haseltine teaches a replication competent HIV-1 virus with a deletion in a non-essential region of the virus and a heterologous DNA inserted. In this case the heterologous DNA is a reporter gene to trace HIV replication or monitor the effects of anti-HIV drugs in a screening assay (abstract and page 4 and 5).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9- 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haseltine, as applied to claims 1, 2, 4, 10, 11 above, and Shi.

As discussed above, Haseltine teaches a replication competent HIV-1 virus with a non-essential region of the virus replaced and a heterologous DNA inserted as a reporter gene to trace HIV replication or monitor the effects of anti-HIV drugs in a screening assay (page 4 and 5).

Haseltine does not teach MT-2 cells or the proviral clone HIV-I Lai.

SHI teaches a similar viral system using the proviral clone HIV-I Lai and uses MT-2 cells to grow the virus.

It would have been *prima facie* obvious to one skilled in the art to substitute other infectious proviral clones or appropriate cell lines to study infection or in an assay for anti-HIV-1 drugs.

Claims 3, 13- 15, 21, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haseltine, as applied to claims 1, 2, 4, 10, 11 above, and Liu.

Haseltine teaches a replication competent HIV-1 virus with a non-essential region of the virus replaced and a heterologous DNA inserted as a reporter gene to trace HIV replication or monitor the effects of anti-HIV drugs in a screening assay (page 4 and 5).

Haseltine does not teach luciferase or SEAP.

Liu teaches that SEAP and Renilla luciferase are useful markers and reporter genes. Also, that there is a mutation in luciferase that makes a better reporter, a cysteine to alanine at position 152 (abstract and Introduction).

It would have been *prima facie* obvious to one skilled in the art to use the reporter gene of Liu because of the advantages taught over reporters.

Claims 5, 6, 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haseltine, as applied to claims 1, 2, 4, 10, 11 above, and Gibbs.

Haseltine teaches a replication competent HIV-1 virus with a non-essential region of the virus replaced and a heterologous DNA inserted as a reporter gene to trace HIV infection or monitor the effects of anti-HIV drugs in a screening assay.

Haseltine does not teach clone pNL4-3 or deletion of some or all vpr.

GIBBS teaches a proviral clone pNL4-3 and that vpr is a non essential region and can be deleted, figures 2 and 3 and Discussion.

It would be *prima facie* obvious to one of ordinary skill in the art to substitute other infectious provirus clones or use different non-essential insertion sites for the reporter gene with the expectation of success.

Art Unit: 1648

Claims 7, 8, 18- 20 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haseltine and Liu, as applied to claims 3, 13- 15, 21, and 22 above, and Collman or Li or Shi.

Haseltine teaches a replication competent HIV-1 virus with a non-essential region of the virus replaced and a heterologous DNA inserted as a reporter gene to trace HIV infection or monitor the effects of anti-HIV drugs in a screening assay.

Haseltine does not teach clone p89.6 or pYU-2.

Collman teaches an infectious clone of HIV-1, p89.6 which has a novel tropism.

Li teaches an infectious proviral clone of pYU-2.

Shi as discussed above teaches the proviral clone of HIV-Lai and the use of MT-2 cells to grow virus.

Knowing the usefulness of Haseltine provirus with reporter gene and assay, one skilled in the art would know that the provirus of Collman or Li or Shi could be used in place of the Haseltine virus.

It would be obvious to one skilled in the art that any HIV-1 provirus with a known sequence could be used in place of the virus of Haseltine with the expectation of success.

### ***Conclusion***

No claim is allowed.

Art Unit: 1648

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 703-308-4521. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4247. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Myron G. Hill  
Patent Examiner  
January 21, 2003

*Mary Mosher*  
MARY E. MOSHER  
PRIMARY EXAMINER  
GROUP 1800  
1600